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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,706	09/11/2003	Simon L. McGurk	029318-0968	4753
31049 7590 02/24/2009 Elan Drug Delivery, Inc. c/o Foley & Lardner 3000 K Street, N.W. Suite 500 Washington, DC 20007-5109				
EXAMINER				
SILVERMAN, ERIC E				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
02/24/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/659,706

**Applicant(s)**

MCGURK ET AL.

**Examiner**

ERIC E. SILVERMAN

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7, 8, 12 and 14-47 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 23, 29 and 44-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 12, 14-22, 24-28, 30-43, 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-5, 7-12, and 14-47 are pending; claims 9-11, 23, 29 and 44-46 are withdrawn; claims 1-5, 8, 12, 14-22, 24-28, 30-43 and 47 are treated on the merits in this action.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 8, 12, 14-22, 26-28, 30-43, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,882,157 to Yang in view of US 6,316,029 to Jain et al.

Yang teaches confectionary delivery systems from anti-cholesterol medicaments. The delivery system includes active drug particles coated with one or more stabilizing materials, such as PEG of instant claim 28. The particles are homogeneously dispersed in gelatin matrices, the matrices comprising gelatin, sweeteners, and other pharmaceutically acceptable materials. The composition has from 1% - 30% water by weight, which substantially overlaps with instantly claimed amount of water. The examples show compositions having the various components within the amounts required by instant claims. The product is formed in rectangular molds, which is a geometric shape. A confectionary is formulated for oral administration. With regard to claim 16, the claim encompasses all types of release profiles, therefore Yang must read

on it. With regard to claim 18, the alternatively recited types of particles encompass all particles, and is therefore read on by Yang. Yang's preferred drug, cholestyramine, is poorly soluble within the meaning of that term in claims 19-21. Yang's teaching of at least one surface stabilizer is suggestive of two, and the oxyethylene taught as a coating reads on nonionic stabilizers of claim 27. Note that the types of gelatin listed in claim 1 are understood to include any gelatin under the sun, so Yang meets this limitation without specifically specifying the type (natural, synthetic, semi-synthetic) of gelatin.

What is lacking from Yang is the particle size.

Jain discloses a composition having a solid dosage matrix, such as gelatin, a poorly soluble active agent having a particle size of less than 2,000 nm and at least one surface stabilizer on the particles. Note that Jain's composition is quite similar to Yang's, except that Jain's composition is dehydrated, whereas Yang's composition is hydrated.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to use the particle sizes of Jain in Yang's composition. Because Yang is silent on the size of the active agent particles, the artisan practicing Yang's invention would look to similar compositions, such as that of Jain, in order to determine the appropriate particle size. Jain provides the particle sizes of instant claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Examiner, Art Unit 1618